Biotechnology Innovation Organization

Submitted via email

September 23, 2016

Andrea Cherepy
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
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RE: TSCA Section 26, application of fees to activities under Sections 4, 5, 6 and 14

Dear Ms. Cherepy

The Biotechnology Innovation Organization (BIO) is the world's largest trade organization representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States. BIO's Industrial and Environmental Section represents over 75 companies, all of whom will be impacted (directly or indirectly) by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which updates the Toxic Substances Control Act ("TSCA"), signed by President Obama on June 22, 2016.[1][2] In advance of the proposed rule for the implementation of fees under the revised TSCA (rTSCA), BIO appreciates the opportunity to provide the following points to consider to the U.S. Environmental Protection Agency (EPA) for EPA's consideration.

BIO member companies range in size, manufacturing capacity and product range but they are all highly innovative, heavily invested in research and development, and responsible for bringing many new, renewable and specialty chemicals to the market. Their biological and biotechnological production systems reduce reliance on petroleum based feedstocks and contribute to mitigating climate change and environmental damage. The use of biotechnology also enables the production of valuable, complex molecules that cannot be produced using traditional chemistry and which can also conserve natural or farmed sources of these products. Examples include the production of emollients previously harvested from shark livers, and oils which can replace the harvesting of fish or of forest habitat. Despite these obvious human health and environmental benefits, BIO member companies have typically faced many more regulatory hurdles than have traditional chemicals simply because they rely more heavily on newer, often safer technologies. Indeed, up until the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, chemicals grandfathered onto the Inventory faced little or no hurdles to their production and use compared to newer chemistries, including those produced using biobased feedstocks or using biotechnology.

[1] Frank R. Lautenberg Chemical Safety for the 21st Century Act
https://www.epa.gov/sites/production/files/2016-06/documents/bills-114hr2576eah.pdf
[2] The Toxic Substances Control Act of 1976 , 15 U.S.C. §2601 et seq. (1976)

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BIO welcomes the fact that existing chemicals which have not been evaluated previously must now undergo prioritization and risk evaluation, as this represents a levelling of the regulatory playing field from a health and safety perspective for all chemicals in commerce today. Now that the new statute has addressed the need to evaluate all existing chemicals on the market, BIO requests that the Agency ensure that it does not tip the balance against newer, safer and renewable chemistries by generating disproportionate financial barriers through a new fee structure.

BIOs comments relate to the principles and rationale for developing the fee structure that EPA now has the authority to implement. Under rTSCA, fees can be assessed up to a maximum of 25% of costs or $25 million per annum, whichever is the lower amount. This represents a significant, approximately 25-fold increase in what the Agency currently obtains in fees through the new chemicals program. Fees may now be leveraged on Section 4 (Testing), Section 5 (Manufacturing and Processing notices), Section 6 (prioritization, risk evaluation and regulation of chemical substances and mixtures) and Section 14 (Confidential Business Information). It is clear that within 3 years of the implementation of the Act, the Agency anticipates that it will be collecting the full $25 million based on its estimates of the increased costs of the additional activities that it must now conduct.

BIO recognizes the additional burden that the new activities required under rTSCA place on the Agency and therefore BIO generally supports fee collection by the Agency versus reliance solely on appropriations.

BIO supports the principle that fees generated under Section 26(b) should be dedicated to the TSCA program rather than going to the Treasury.

BIO requests that the Agency implement its fee structure in a manner which reflects the TSCA policy articulated in Section 2(b), which states that "authority….should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation". In short, the application of fees should not give rise to another, different slew of barriers to innovation and commercialization to our members on top of those already in place.

BIO would like the fee structure to reflect the effort expended by the Agency in conducting these activities under these sections. In time, this effort should be accurately captured and used to revise the fees every three years, as authorized in Section 26(b).

EPA's primary role is the protection of human and environmental health and safety. In fulfilling this role, EPA should be cognizant of how regulation and its associated costs impact the chemical landscape in the United States and, indeed, can detract from the overarching goal of enhancing health, safety, and environmental values. Such costs have a powerful effect on an individual company's ability to invest in research and new product development, and a country's overall competitiveness in that sector. For this reason, the implementation of fees should, at the least, be technology and feedstock neutral, and certainly should not discourage or be biased against the development of new, safer

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molecules from renewable sources utilizing production technologies which are more environmentally friendly.

Neither should fee requirements inadvertently increase costs to US bio-based chemical manufacturers relative to manufacturers of the same chemistries in other countries. Careful consideration should be given to how EPA fees may or will affect the direction and competitiveness of US chemical industry as it evolves into the future, and how chemicals are regulated by other trading partners such as the EU.

BIO members' concerns:

BIO has several overarching concerns over how these fees will be applied across the four sections of rTSCA. Broadly, these concerns relate to short-term, medium-term, and long-term impacts on innovation, new product development, and competitive standing, and are particularly relevant to companies which manufacture or process new chemicals and chemicals produced using biotechnology, and to small companies and start-ups. These concerns, and the principles on which BIO can support the application of fees, are outlined below:

General remarks:

1. **The determination of overall costs against which fees are assessed:**

In order to meet the rTSCA requirement that fees be "sufficient and not more than reasonably necessary" to defray up to 25% of the costs of administering Sections 4, 5, 6 and 14, EPA must be clear about its current and anticipated costs, and realistic in its expectations for fee revenue. BIO requests the Agency provide **an options paper** which models various fee options and provides preliminary estimates of the economic impact of a fee, as EPA did in July 1986.[3] The options paper should be circulated for public consultation prior to publishing apart of or prior to a proposed rule. The Agency has the opportunity to better define its costs over the next three years as the Agency ramps up its activities under rTSCA, Furthermore, the Agency will have to develop more detailed information on the costs of administering Sections, 4, 5, 6 and 14 than that which is currently available in order to meet audit requirements under Section 26(b)(3)(D)(ii). Additionally, under Section 26(b)(F), EPA is obliged, every 3 years after the date of enactment, to consult with parties potentially subject to the fees and to review and adjust the fees accordingly. BIO urges the Agency to ensure that the costs on which they base the application of fees now and going forward are sufficiently detailed, transparent and publicly available.

2. **The definition of and application of fees to small businesses**

Under Section 26(b)(4)(B), the aggregate total of TSCA fees cannot exceed $25 million. In addition, lower fees for small businesses must be established in consultation with the Small Business Administration. (See Section 26(b)(4)(A))

[3] 51 Fed. Reg. 25250 (July 11, 1986)

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Much of the innovation in new safer chemistries and production technologies comes from smaller companies and start-ups. At the same time, small businesses are disproportionately affected by regulatory requirements because they increase costs and staffing needs. This is particularly significant when the company's product portfolio is small or when the product has not yet begun to generate revenue. BIO therefore supports the continued implementation of lower fees or fee exemptions for small businesses and start-ups.

BIO would also like the current TSCA definition of a "small business" to be updated as it is currently outdated (from 1986) and too small. Specifically, the value of sales within the definition of a small business needs to be substantially increased to reflect inflation. BIO requests the Agency take into consideration the fact that in this globalized economy, small businesses may none the less have foreign sales, and this should not be used to penalize them from a fee perspective. Small businesses also include start-up companies which have not yet generated revenue from commercializing their product, but which are existing on investment funding and are still at the research and development phase. Investment funding should not be counted towards the threshold used for defining a small company. BIO also requests the Agency consider a minimum sales value threshold for companies below which they may be exempted from fees, not unlike the lower bound threshold currently applied for requiring chemical data reporting (CDR). This would recognize the fact that many start-ups have no reliable or commercially meaningful revenue stream but still have onerous costs associated with meeting TSCA regulatory requirements.

3. **Weighting of the fees across the sections:**

The Agency has requested input on how the fees should be weighted across the various sections of rTSCA, as their weighting could indirectly penalize or favor new versus existing chemicals. Fees applied for activities under Section 5 (new chemicals) will disproportionately impact small and start-up companies, precisely because these companies drive innovation and the development new chemicals which, precisely because they are new, have not yet generated reliable revenue streams.

Prior to its amendment this year, TSCA could only be implemented in a manner which was biased towards the continued use of existing and grandfathered chemicals. BIO requests that the Agency ensures that fees do not act to disincentivize innovation and the development of new chemicals, particularly if those chemicals and their production methodologies represent safer or more environmentally friendly alternatives to incumbents on the inventory. BIO therefore suggests that the Agency collects fees for activities in all sections, but that those fees are weighted to prevent a disproportionate or excessive fee burden on the development of new chemicals, new microbes, or the administration of Confidential Business Information (CBI) requirements. Again, BIO supports the implementation of reduced fees and/or exemptions from fees across all sections for small businesses and start-ups.

Prior to revising TSCA, it was the regulation of new chemicals which generated fees. BIO

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does not support the continued use of Section 5 as the main source of fee revenue for the Agency, particularly those activities associated with TERA, PMN and MCAN submissions, as this could inhibit the development of new chemicals and new microbes, and act as a disproportionate financial hurdle to small businesses and start-ups. Weighting fees towards these type of filings would also discourage the utilization of new chemical alternatives in the chemical value chain, as new chemicals typically give rise to PMNs further downstream as those chemicals are converted and used in the manufacture of other chemicals and products.

That said, BIO notes that the fewer the sections or activities on which fees are levied, the more the other sections or activities will have to bear the total costs. In addition, while there are activities for which fees are not currently assessed, there is nonetheless a cost to the Agency associated with conducting these activities, such as data input and storage for example. For this reason, consideration should be given to assessing nominal fees on activities under Section 4 and 14, with reductions or exemptions for small businesses and start-ups respectively. Nominal fees, spread across the entire industry, should help contribute to the overall efficiency with which the Agency conducts these activities and should enable the allocation of resources such that the Agency can apply efforts as needed across all sections.

4. Assessment, use and refunds of the fees collected

In principle, the fees collected should be allocated in support of the actions taken by the Agency in implementing the sections under which those fees are collected. Fees from one section should not be cannibalized to support other sections. However, there may be alternative approaches to this depending on an evaluation of various options and their economic impact, thus BIO urges the Agency to conduct a review of these and the development of an Options Paper, as outlined in the first point "The determination of overall costs against which fees are assessed". One option, for example, is the broad application of nominal fees or overhead for indirect costs, or OPPT-wide activities required to support Sections 4, 5,6 and 14, such as the development of databases and data input.

BIO supports a simple and easily understood and administered fee structure. The current fee structure for new chemicals has the benefit of being straightforward and familiar to manufacturers. It includes fees on PMNs, reduced fees on intermediates and for small businesses, and the ability of submitters to consolidate numerous PMNs into one submission. This latter approach is very helpful in reducing the burden on industry and the Agency but is unfortunately far more difficult for manufacturers of biobased products to implement, giving rise to multiple redundant PMNs as a result. The Agency should recognize this, and develop approaches to reducing this disproportionate burden on biobased product manufacturers, including careful consideration of the interpretation of the new nomenclature language. Failing to do this will result in the continued penalization of manufacturers of renewable chemicals and act against the development of environmentally friendly, safer chemical alternatives.

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EPA historically has not charged fees for applications for exemptions under Section 5(h). This includes Test Market Exemptions, Low Volume Exemptions, and Low Release-Low Exposure (LoREX) exemptions. BIO believes that EPA should not change its practice and start charging fees for exemption applications, but in the interests of spreading the costs across all sections and activities, BIO is not opposed to the imposition of fees for exemption requests **but only if they are low, and capped**. – This is because activities qualifying for an exemption tend to be extremely restrictive in volume, manufacturing methods, and end use applications, and therefore do not raise the same concerns regarding health or environmental risks that larger volume notifications do. Additionally, exemption notices have shorter review times and do not require as much EPA resources as a PMN review does. BIO would be happy to continue to engage in dialogue with the Agency and other stakeholders as the Agency seeks to provide proper definition to such concepts as "nominal" and "low" in this context.

EPA now has to refund a PMN submitter if EPA misses its 90/180-day deadlines (See section 5(3)(4)). We believe an appropriate timeframe to refund a submitter in such cases should be fixed, and within 30 days of missing the deadline.

5. Treatment of Confidential Business Information (CBI)

BIO is concerned about the potential impact of charging specific fees for making Confidential Business Information (CBI) claims. Penalizing CBI claims by applying fees is essentially a tax that acts as a disincentive to innovation. Furthermore, companies will now have to provide more information to EPA in order to substantiate a claim, which will result in an increased cost burden on top of whatever fees may also be levied. While there may be Agency costs associated with collating, tracking, reviewing and protecting CBI, new technologies need to be protected in order to ensure the US industry can capture a return on investment and thereby continue to innovate, grow, create new manufacturing jobs and remain competitive. In other words, the benefits of protecting CBI accrue to society as a whole, not just to the individual company. Further, the ability to compete is not solely a function of industry innovation and investment, but a function of how a country chooses to regulate and to protect the CBI it receives in order to do so. We urge the Agency to continue to protect CBI without relying on this activity as a source of fee revenue, in order to prevent the penalization of innovation and competition. If necessary, the Agency may wish to consider fees for CBI protection as an overhead under Section 6.

Specific remarks on the Application of fees to Sections 4, 5, 6 and 14.

Section 4 fees - Testing:

The Agency has been provided with the authority to mandate testing. The cost of testing is currently unknown and, depending on what the Agency requires, could involve considerable time and expense. Because the additional data generated by this testing will be used to evaluate PMNs, prioritize, and/or conduct a risk evaluation, fees should not be collected for the review of data submitted under Section 4, if these data will be reviewed as part of the

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activities in Sections 5 and 6. At most, a nominal fee for the submission of data should be collected, to assist the Agency in covering the cost of issuing test orders or managing the data submitted. Small businesses and start-ups should be exempted.

Section 5 fees – New Chemicals:

BIO requests the Agency consider different or tiered fee schedules for different filing activities (PMNs, MCANs, SNURs and TERAs) depending on the effort required to review each filing, and the impact it is likely to have on innovation and on small businesses. For example, TERAs and PMNs are required during the research and development stage, pre-commercialization, and pre-manufacture – in other words, at the innovation stage and before the chemical has generated any revenue. Fees at this stage of product development can disproportionately impact innovation and new product development – particularly by small business start-ups - compared to fees applied after a product has been manufactured and sold, when the company is earning revenue from the product. SNUNs, for example, are required post commercialization and subsequent to a PMN, so presumably revenue has already been generated. Fees should also reflect the effort required - a NOC is simply a notification that manufacturing is about to begin, and requires relatively little review effort compared to other filings. Thus BIO requests the Agency consider the stage of the development cycle, the ability of the company to support the cost of the filing relative to the revenue generated by the compound, and the complexity of the review or effort required when developing the fee schedule for these various filings.

As a matter of principle, fees should be weighted so as not to stymie innovation and discourage new products from being brought to the market. However in its estimates of the activities required under Section 5, EPA has already assumed a 30% reduction in PMN submissions due to an increase in PMN filing fees. This is concerning. The expectation should be that any new fees would, at the least, have a neutral effect on the number of new chemicals being developed.

BIO member companies are concerned about and specifically request the Agency address the proliferation of PMNs that occurs by virtue of how chemicals produced using microbes or biobased feedstocks must be notified to the Agency, and the application of nomenclature used to describe chemicals and therefore whether or not they are considered "new". This specifically and disproportionately militates against renewable chemical manufacturers and therefore against technologies which confer human and environmental health benefits to society. It has stymied the growth of many small companies and start-ups, and acted against the use of renewable feedstocks and biotechnology for product manufacture and their use in the value chain:

EPA insists multiple filings are made for equivalent chemicals if the source of the chemical is different. The source could be either the microbe or feedstock used to produce the chemical regardless of risk. For example, for every chemical produced using a microbe, with few exceptions, two PMNs, not one, must be submitted (an MCAN and a PMN). In addition, when a chemical is produced using a microbe, any changes made to that that microbe to improve or increase production requires a PMN be filed for the chemical it produces, even if the

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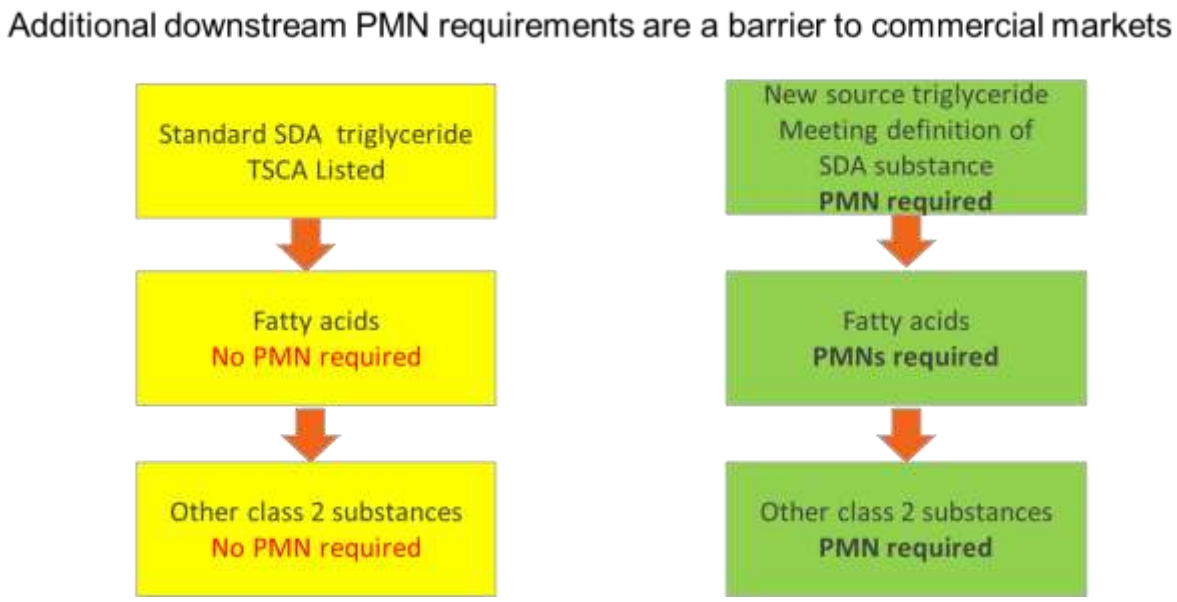
chemical is equivalent. (As well as requiring another MCAN for the altered microbe, even if the alterations have no impact on the risk they may pose). Then, if customers are testing and using the chemical, they must file multiple PMNs for what they should be able to consider a "drop in replacement" for an existing chemical substance on the TSCA inventory. This results in a proliferation of PMN submissions for chemistries which are actually identical. In turn, this has acted to make difficult, or even prevent, the use of safer biobased chemical alternatives by processors and consumers because of the downstream regulatory filing requirements and associated costs (time, staff, and filing fees).

The following example based on the production of a triglyceride – identical in both cases except the source – illustrates how this occurs:



EPA is well aware of this PMN proliferation issue for bio based materials, and it could be greatly exacerbated by higher fees. BIO requests that EPA consider a different fee structure for chemicals produced using biotechnology and biobased feedstocks, which would allow companies to group similar chemicals and/or microbes together under one application fee. Such an approach would align with the EPA Green Chemistry program. In addition, it should be possible to reduce or tier fees for new chemicals which require MCAN submissions in addition to PMNs as this otherwise equates to charging for two filings when there is only one chemical is being notified to the Agency.

As the Agency considers fees for reviewing the various submissions under Section 5, BIO acknowledges that inflation may be an appropriate metric for updating the fees associated with these activities. Again, we support the implementation of significantly lower fees for small businesses and start-ups to encourage their growth, development and continued

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Section 6 fees – Existing Chemicals:

Under Section 6 EPA is now mandated to prioritize and risk evaluate "active" chemicals on the TSCA inventory. EPA must have, within 3.5 years of enactment, 20 high risk chemicals going through the risk evaluation process. This represents a significant increase to EPA's current workload. Fortunately and for good reason, the Agency is not authorized to conduct risk evaluations on chemicals designated as "low risk", simply to identify 20 such chemicals per annum not later than 3.5 years after the date of enactment.

Prioritization: There are approximately 84,000 chemicals on the current TSCA inventory, which following the Inventory Reset must be prioritized by the Agency for risk evaluation. It is entirely unclear what the cost of prioritization will be, as this depends entirely on how the Agency chooses to conduct this activity. In the short to medium term, the chemicals will be drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments. There are flaws in this approach that have been previously articulated by industry, and there is no clarity on how the EPA's Office of Research and Development TOXCAST and EXPOCAST could be used for screening purposes and to reduce costs to industry and the Agency. Either way, BIO is assuming that prioritization for previously un-reviewed chemicals will not be without cost, regardless of whether or not the chemical is determined to be low or high risk.

In summary, BIO does not believe the statute requires the Agency to charge a fee for every single activity it conducts under Sections 4, 5, 6 and 14 and BIO does not support the application of fees for prioritization to new chemicals which have already been risk evaluated prior to inclusion on the TSCA inventory through the PMN review process. BIO recommends the Agency ensures that the fees reflect the effort required, thus the Agency may choose to impose fees only on chemicals which have not been subject to review, or to roll the cost of prioritization into the fees for risk evaluation. EPA may wish to apply a nominal fee across all chemicals on the inventory subject to prioritization activities but such fees should not penalize new chemicals or innovation.

Risk Evaluation: Risk evaluation is not a one- size- fits-all approach, because chemicals differ in their hazard characteristics and their use / potential exposure. Risk evaluation is the most expensive component of the activities on which the Agency can collect fees, according to EPA's own estimates and based on our knowledge of the work that a risk evaluation entails. Risk evaluations take longer than Section 5 activities – and the Agency has been given between 3 and 3.5 years to complete each one. For this reason we recommend the Agency tie the collection of fees to specific activities within the risk evaluation process, such as the development of the scoping document, the development of the draft risk evaluation, and the final risk evaluation, thereby splitting the costs over time. Because of the effort required under section 6, BIO supports Section 6 being the driver for enabling the EPA reach its fee collection targets under rTSCA (25% of costs or $25 million), not Section 5.

Consortia: Finally, the Agency has the opportunity to enable industry-led consortia to

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address the cost of activities under Section 6. This could include data generation but also fee distribution and collection. The EU has developed specific approaches for enabling such consortia to address costs associated with chemicals produced or used by multiple manufacturers and processors, which have worked well. Consortia have also been effective in spreading the costs associated with the re-review of generic pesticides under FIFRA. There are caveats to this approach - for example, the fees associated with joining a consortium can be prohibitive for smaller manufacturers. Nonetheless, this can be a useful way in which costs can be spread across all manufacturers and/or processors involved in the production and use of a particular chemical.

Section 14 fees – Confidential Business Information

The new TSCA now requires EPA to review a substantial number of CBI claims, and EPA has the discretion to recover those costs through the application of fees. CBI is a fundamentally important part of protecting and nurturing innovation, and is a critical component of returns on investment. As many of BIO's member companies survive on investor funding until they can earn a return from the market, the cost of protecting CBI should not be such that it stymies their innovation, or investor confidence and funding. EPA should therefore carefully assess and tread gently in applying specific fees to this aspect of their work.

BIO would prefer that fees are not levied on the review or protection of CBI at all. If fees are deemed necessary to support CBI review activities, then the burden should fall on existing chemicals notified as "active" as part of the inventory reset. This would have a lesser impact on innovation and new product development. CBI is not only a commercial good, but a public good – in that it enables the growth and development of new technologies that benefit society and the growth of companies and new job creation which arises as a result. If additional funding is required to support the infrastructure necessary to administer and support the collection, storage and protection of CBI provisions, then any such fees should be nominal, spread equitably across all manufacturers and processors, and capped.

BIO thanks EPA OPPT for its time and consideration of our comments. We appreciate that EPA is working diligently to implement the many obligations it has under the revised TSCA. We hope our comments are helpful and if you have any questions or require clarification, please feel free to contact us.

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